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| 10/006,158      | 12/10/2001  | William H. Wall      | W6-19a              | 2016             |

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/29/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/006,158

Applicant(s)

WALL, WILLIAM H. CN

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed 5/12/03 has been entered as Paper No. 7. Changes to the specification and claim 1 have been approved by the examiner. Under "Introductory Comments", applicant states that a new abstract is being submitted with the amendment. However, the new abstract was not included. Examiner requests that a copy of the new abstract be included in response to this office action.

### *Specification*

2. The objection to the abstract of the specification is maintained. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word "said" on line 7 is legal phraseology that must be deleted.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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X 4. Claims 6 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims require that the "sheath surrounds said structural frame" and "sheath extending about said frame", respectively, on lines 1 and 6. There is no support in the specification or the drawings for these limitations. The specification and drawings only disclose the rods of the frame as being secured or affixed to the sheath, but not specifically that the sheath *surrounds* or *extends about* the frame. In fact, it appears from Figures 1 and 2 that the opposite is being disclosed, specifically that the frame is actually surrounding or extending about the sheath.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ 6. Claim 1 recites the limitations "the uncoiled position" and "the inner surface" in lines 15 and 17. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests changing "the" to --an-- in both clauses.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clouse in view of Lam.

Clouse discloses a blood vessel wall-defining device for repairing an aneurysm having all the claimed elements of claim 1, except for the ring stents and their respective limitations. See abstract for a structural frame being a combination of Figure 1 (structural skeleton 30) and Figure 2 (tubular membrane 40) and for the structural frame having a smaller unexpanded diameter and a larger expanded diameter than the blood vessel. See Figure 2 the structural frame (combination of 30 and 40) including a plurality of longitudinal support rods (46) being attached to a tubular sheath (41) for at least a portion thereof. Lam teaches an expandable coiled stent (claims 4 and 7; see Figures 5B-6B for the coiled stents being expandable to selected progressively uncoiled positions in order to meet the functional language of the structural frame being *capable* of being expanded to different breadths along its length and urging the structural frame toward engagement with the interior surface of an irregularly shaped vessel) having controlled expansion that can be locked into an expanded diameter in order to prevent collapse of the stent. See Figures 5A-5C and column 7, lines 15-28. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lam to modify the blood vessel wall-defining device of Clouse by replacing the expansible spring coil

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(48) disposed on the interior of the tubular sheath (41) with a plurality of the ratcheted ring stents of Lam in order to have controlled expansion of the device along the longitudinal length of the device in addition to preventing the device from collapsing.

Claim 5, see column 3, lines 27-29 for longitudinal support rods (46) being flexible capable of performing the function of conforming to the shape of the vessel between the ring stents.

With respect to claim 9, see rejection to claim 1, supra. The plurality of elongated flexible support members (46) are arranged approximately parallel to one another and formed in a tubular array for insertion into a blood vessel of the human body (Figure 2). The plurality of ring stents are structurally capable being expanded in response to the inflation of a balloon catheter and of meeting the functional language of urging the elongated flexible support members from their unexpanded diameter to the expanded diameter. The elongated flexible support members of Clouse are configured to support the blood vessel at the positions between the ring stents.

***Allowable Subject Matter***

9. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

10. Applicant's arguments filed 5/12/03 have been fully considered but they are not persuasive.

11. Applicant argues that Clouse discloses a two-piece assembly while applicant's product has a structural frame that includes a plurality of longitudinal support rods with a sheath connected thereto and ring stents carried with the frame. Examiner directs applicant's attention to the preamble of claims 1 and 9, which claim a "blood vessel wall defining device". The two pieces of Clouse, when combined together in the body, form a blood vessel wall defining device.

12. In response to applicant's argument that the references fail to show certain features of applicant's invention, as required by claim 1, it is noted that the features upon which applicant relies (i.e., the device can be positioned with the ring stents displaced from the intersecting artery or from the aneurysm so as to avoid obstruction of blood flow or to avoid the application of excessive stress against the wall of the vessel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir, 1993).

13. Examiner appreciates that applicant's stent device *as disclosed* is structurally and functionally different from the applied references, but it is not different in how it is claimed. Claim 1 simply requires certain structural elements in combination to form a blood vessel wall defining device, the elements being an expandable frame including longitudinal support rods attached to a tubular sheath having a plurality of ratcheted ring stents longitudinally displaced internally therein. There is no mention of how the device is being expanded that would provide a structural difference between it and that of Clouse, as modified by Lam. Claim 9 requires that

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the plurality of ring stents be configured to expand in response to an inflating balloon catheter and arranged to urge the elongated flexible support members from their unexpanded diameter to their expanded diameter. The ring stents of Lam are indeed configured to be expanded by a balloon and, when applied to Clouse, are indeed *capable* of urging the elongated flexible support members from their unexpanded diameter to their expanded diameter. The way claim 9 is currently written, it is not required the elongated flexible support members be expanded by the balloon expanded ring stents, but only that the ring stents are structurally capable of expanding them. In that regard, replacing the spring coil of Clouse with ring stents of Lam does not destroy the device of Clouse. The device with the ratcheted ring stents (claim 1) is still able to expand in response to the high temperature of the body. The rings stents will simply prevent the device from collapsing.

### *Conclusion*

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

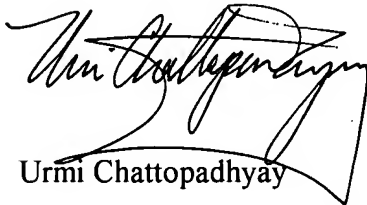


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David H. Willse  
Primary Examiner

uc

July 23, 2003